Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Proposed Registration Decision PRD2016-32

Pyraflufen-ethyl

(publié aussi en français)

19 October 2016

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2016-32E (print version)
H113-9/2016-32E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2016

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

Overview 1
Proposed Registration Decision for Pyraflufen-ethyl 1
What Does Health Canada Consider When Making a Registration Decision? 1
What Is Pyraflufen-ethyl? 2
Health Considerations 2
Environmental Considerations 4
Value Considerations 5
Measures to Minimize Risk 5
Key Risk-Reduction Measures 5
Next Steps 6
Other Information 6
Science Evaluation 7
1.0 The Active Ingredient, Its Properties and Uses 7
2.0 Methods of Analysis 7
2.1 Methods for Analysis of the Active Ingredient 7
3.0 Impact on Human and Animal Health 7
4.0 Impact on the Environment 8
4.1 Fate and Behaviour in the Environment 8
4.2 Environmental Risk Characterization 9
4.2.1 Risks to Terrestrial Organisms 10
4.2.2 Risks to Aquatic Organisms 12
5.0 Value 14
6.0 Pest Control Product Policy Considerations 14
6.1 Toxic Substances Management Policy Considerations 14
6.2 Formulants and Contaminants of Health or Environmental Concern 15
7.0 Summary 15
7.1 Human Health and Safety 15
7.2 Environmental Risk 16
7.3 Value 16
8.0 Proposed Regulatory Decision 16
List of Abbreviations 17
Appendix I Tables and Figures 19
Table 1 Fate and behaviour in the terrestrial environment 19
Table 2 Fate and behaviour in the aquatic environment 20
Table 3 EECs in soil and water* 20
Table 4 Level 1 aquatic ecoscenario modelling EECs (µg a.i./L) for pyraflufen-ethyl combined residue in a water body 0.8 m deep, excluding spray drift 21
Table 5 Level 1 aquatic ecoscenario modelling EECs (µg a.i./L) for pyraflufen-ethyl combined residue in a water body 0.15 m deep, excluding spray drift 21
Table 6 Revised Level 1 aquatic ecoscenario modelling EECs for pyraflufen-ethyl combined residue in a water body 0.8 m deep, excluding spray drift. Based on new maximum application rate of 9 g a.i./ha 21

Table 7 Revised Level 1 aquatic ecoscenario modelling EECs for pyraflufen-ethyl combined residue in a water body 0.15 m deep, excluding spray drift. Based on new maximum application rate of 9 g a.i./ha 22
Table 8 Major groundwater and surface water model inputs for Level 1 assessment of pyraflufen-ethyl and its major transformation products E1, E2, E3 and E9 22
Table 9 Toxicity of pyraflufen-ethyl and its end-use product to terrestrial organisms 23
Table 10 Toxicity of pyraflufen-ethyl, its end-use product and the major transformation product E1 to aquatic organisms 24
Table 11 Endpoints used in the risk assessment 25
Table 12 Risk to terrestrial invertebrates and plants 26
Table 13 Risk to birds and mammals (Screening assessment; overspray at 4.5g a.i./ha × 1) 27
Table 14 Risk to aquatic organisms from pyraflufen-ethyl herbicide 27
Table 15 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria 29
References 31

Overview

Proposed Registration Decision for Pyraflufen-ethyl

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Nufarm Pyraflufen-ethyl Technical and Pyro Herbicide (previously known as NUP6D 04 Herbicide), containing the technical grade active ingredient pyraflufen-ethyl, to be used for control of emerged broadleaf weeds prior to the emergence of wheat (spring, durum, and winter), barley, oats, rye (spring and fall), triticale, buckwheat, pearl millet, proso millet, canola, mustard, peas, beans, lentils, corn and soybean.

Nufarm Pyraflufen-ethyl Technical (Registration Number 31257) and Pyro Herbicide (Registration Number 31258) are conditionally registered in Canada. A bioconcentration study for E3, one of the transformation products, was requested as a condition of registration. The detailed review for Nufarm Pyraflufen-ethyl Technical and Pyro Herbicide can be found in Evaluation Report ERC2014-03, *Pyraflufen-ethyl*, with additional updates in this document. The current applications were submitted to convert Nufarm Pyraflufen-ethyl Technical and Pyro Herbicide from conditional registration to full registration.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Nufarm Pyraflufen-ethyl Technical and Pyro Herbicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

---

1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on pyraflufen-ethyl, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on pyraflufen-ethyl, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Pyraflufen-ethyl?

Pyraflufen-ethyl is the active ingredient in the end-use product Pyro Herbicide. It belongs to the phenylpyrazole chemical family and is a contact herbicide for control or suppression of several emerged broadleaf weeds, specifically lamb's-quarters, redroot pigweed, volunteer canola, dandelion, flixweed, wild buckwheat, kochia and stinkweed, prior to the emergence of wheat (spring, durum, and winter), barley, oats, rye (spring and fall), triticale, buckwheat, pearl millet, proso millet, canola, mustard, peas, beans, lentils, corn and soybean. As an inhibitor of protoporphyrinogen oxidase (PPO), pyraflufen-ethyl results in cell membrane destruction and necrosis. The foliage of sensitive plants turns yellow and brown with leaf burn, followed by death of the whole plant.

Pyraflufen-ethyl is classified as a Group 14 herbicide by the Weed Science Society of America and as a Group E herbicide by the Herbicide Resistance Action Committee.

Health Considerations

Can Approved Uses of Pyraflufen-ethyl Affect Human Health?

Pyro Herbicide, containing pyraflufen-ethyl, is unlikely to affect your health when used according to the proposed label directions.

Potential exposure to pyraflufen-ethyl may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The

---

3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the technical grade active ingredient pyraflufen-ethyl was of low acute toxicity by the oral, dermal and inhalation routes of exposure. Pyraflufen-ethyl was minimally irritating to the eyes and non-irritating to the skin, and did not elicit an allergic skin reaction. Consequently, these findings do not trigger a requirement for hazard labelling.

The end-use product Pyro Herbicide, containing pyraflufen-ethyl, was of low acute toxicity via the oral, dermal and inhalation routes of exposure. It did not cause an allergic skin reaction. It was severely irritating to the eyes and extremely irritating to the skin. Consequently, the hazard signal words "DANGER – CORROSIVE TO EYES AND SKIN" are required on the label.

Registrant-supplied short- and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature, were assessed for the potential of pyraflufen-ethyl to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints used for risk assessment were effects on the liver, which included tumours in mice, and reduced fetal survival occurring at a dose that produced toxicity to the maternal animal. There was no indication that the young were more sensitive than the adult animal. The risk assessment protects against these and any other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and children 1-2 years old, the subpopulation that would ingest the most pyraflufen-ethyl relative to body weight, are expected to be exposed to less than 1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from pyraflufen-ethyl is not of health concern for all population subgroups.

The lifetime cancer risk from the use of pyraflufen-ethyl on the registered crops, including field corn, soybeans and wheat, is not of health concern.

Animal studies revealed no acute health effects. Consequently, a single dose of pyraflufen-ethyl is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States, including representative Canadian growing regions, using pyraflufen-ethyl on field corn, soybeans and wheat are acceptable. The MRLs for this active ingredient can be found in ERC2014-03.

Occupational Risks from Handling Pyro Herbicide

Farmers and custom applicators that mix, load or apply Pyro Herbicide can come in direct contact with pyraflufen-ethyl residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Pyro Herbicide must wear long pants, a long-sleeved shirt, socks and shoes. In addition, workers mixing and loading must wear chemical resistant gloves, and goggles or a face shield. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, health risk to these individuals are not of concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Pyraflufen-ethyl Is Introduced into the Environment?

When used according to label directions, pyraflufen-ethyl is not expected to pose risks of concern to the environment.

Pyraflufen-ethyl enters the environment when it is used as an herbicide for control of weeds on a variety of crops. Spray drift from ground applications and run-off from the site of application can enter non-target terrestrial and aquatic habitats. In both soil and water, pyraflufen-ethyl transforms quickly and is not expected to bioaccumulate. The major transformation products formed in soil and/or water are non-persistent to persistent and are not expected to bioaccumulate. Although pyraflufen-ethyl is not likely to leach to groundwater, some of the major transformation products have the potential to leach through the soil profile and enter groundwater.

Overall, pyraflufen-ethyl and its major transformation products present a negligible risk to pollinators, birds, small mammals and fish (freshwater and marine). However, pyraflufen-ethyl may affect beneficial arthropods, terrestrial plants, freshwater algae and amphibians. To reduce

exposure of terrestrial plants and aquatic organisms, spray buffer zones between sites of application and non-target areas are required. Precautionary label statements will be used to inform users of all risks to the environment and to help reduce the potential for surface runoff.

Value Considerations

What Is the Value of Pyro Herbicide?

Pyro Herbicide may be applied prior to seeding or emergence of wheat (spring, durum, and winter), barley, oats, rye (spring and fall), triticale, buckwheat, pearl millet, proso millet, canola, mustard, peas, beans, lentils, corn and soybean at rates up to 9.0 g a.i./ha in combination with a non-ionic surfactant at 0.25% v/v, to combat infestations of emerged broadleaf weeds; specifically to control lamb's-quarters and redroot pigweed and to suppress volunteer canola, dandelion, flixweed, wild buckwheat, kochia and stinkweed. Pyro Herbicide may be applied once per growing season by ground application equipment.

There are several Group 14 herbicides registered for application prior to crop emergence for control of emerged weeds, but none belong to the phenylpyrazole chemical family. The value of Pyro Herbicide relates to its potential contribution to herbicide resistance management as well as providing growers an additional weed control option within the Group 14 mode of action category.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Pyro Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Environment

- Advisory statements to inform users that pyraflufen-ethyl can be toxic to non-target organisms including beneficial arthropods, terrestrial plants, amphibians, freshwater fish and algae.
- Advisory statements to inform users of conditions that may favour run-off and leaching.
- Spray buffer zones to protect terrestrial and aquatic habitats from drift.
- A label statement encourages users to take measures to reduce the build-up of persistent soil transformation products.

Next Steps

Before making a final registration decision on pyraflufen-ethyl, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document.

Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on pyraflufen-ethyl (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

An evaluation report, ERC2014-03, *Pyraflufen-ethyl*, provides a summary of data reviewed and the rationale for the regulatory decision. The information captured herein relates to new information provided to the Agency in support of a conversion from conditional to full registration.

Pyraflufen-ethyl

1.0 The Active Ingredient, Its Properties and Uses

For details on the identity of the active ingredient, the physical and chemical properties of the active ingredient and the end-use product, the directions for use and mode of action refer to ERC2014-03.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

For details on the methods of analysis refer to ERC2014-03.

3.0 Impact on Human and Animal Health

For a summary of the previously reviewed toxicology, occupational exposure and dietary exposure data for pyraflufen-ethyl, as well as the toxicology endpoints for use in the human health risk assessment, refer to ERC2014-03.

After the conditional registration was granted, the registrant amended the end-use product to add new crops and new weeds, to increase the application rate, change the level of control for some weeds, and to make minor label amendments. An updated health risk assessment was conducted and no health risks of concern were identified from the use of the end-use product, Pyro Herbicide, provided that workers wear the appropriate personal protective equipment and follow all label directions.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents to the PMRA, including diverse effects to Canadian health or the environment. The PMRA database was searched for incident reports involving pyraflufen-ethyl. As of 25 May 2016, the PMRA had received no incident reports related to Canadian health or the environment.

In addition, no environmental incident reports were found in a search conducted using the USEPA's Ecological Incident Information System (EIIS).

4.0 Impact on the Environment

A detailed review of the environmental database for pyraflufen-ethyl was conducted previously and is summarized in ERC2014-03.

4.1 Fate and Behaviour in the Environment

Data on the fate and behaviour of pyraflufen-ethyl and its major transformation products are summarized in Appendix I, Tables 1 and 2.

Pyraflufen-ethyl enters the environment when used as an herbicide for control of weeds on a variety of crops. When applied, pyraflufen-ethyl will primarily come in contact with soil. It is carried from the area of application by drift and run-off. In both soil and water, pyraflufen-ethyl transforms quickly, with biotransformation being the major route of dissipation and with hydrolysis and phototransformation contributing to a lesser extent. Major transformation products include E1, E2 and E3. The transformation product E1 is soluble, mobile and moderately persistent and is expected to reach ground and surface water. The transformation products E2 and E3 are persistent in soil and aquatic systems and tend to adsorb to soil and sediment, with residues in soil carrying over to the next season and accumulating over time.

Pyraflufen-ethyl has low mobility in soil and is not expected to leach. The transformation product E1 is moderately to highly mobile in soil and meets the criteria for a leacher and borderline leacher. The transformation products E2 and E3 are classified as having slight to low mobility and are not expected to leach. In laboratory studies, pyraflufen-ethyl and E1 did not leach below 15 cm and essentially none of the applied material was found in the leachate collected from the soils. Due to the low leaching potential of pyraflufen-ethyl and transformation products E2 and E3, they are expected to have a low potential to reach groundwater or to reach surface waters through runoff. However, because some of the transformation products are persistent in soil, groundwater modelling indicates that residues can reach groundwater after a period of continued use.

In field studies, pyraflufen-ethyl dissipated quickly, having a half-life of less than one day. The major transformation products observed were El and E3. The study from Washington showed both major transformation products were persistent. Leaching was limited, with nearly all residues being detected in the top 15 cm soil layer. This is in agreement with laboratory studies where a similar accumulation of the above transformation products was observed, and a similar lack of extensive leaching. These results show that major transformation products are persistent in soil, and carryover of pyraflufen-ethyl residues from season to season can be expected, resulting in accumulation in the soil.

In water, pyraflufen-ethyl is rapidly transformed (half-life of < 6 hours) by microorganisms in aerobic and anaerobic aquatic systems. The major transformation products include E1, which is moderately persistent in the water phase and E2, which partitions to sediment in addition to the minor transformation product E3.

All three transformation products are persistent and could accumulate over time. Available information on the transformation product E1 indicates that it has low bioconcentration potential in rainbow trout. No information on the bioconcentration potential of the transformation product E3 was submitted.

A bioconcentration study of E3 in fish was requested at the time of the original registration which made the registration of pyraflufen-ethyl conditional. The registrant submitted modelling results instead as a waiver for the laboratory study. The modelling results were not considered to be adequate to determine the BCF value.

Due to the absence of reliable information on bioconcentration of E3, the potential toxicity of E3 was reconsidered by PMRA. Based on chemical structures and the transformation pathway of the parent compound (pyraflufen-ethyl) to E1 to E2 to E3, PMRA has determined that the toxicity of E3 to fish, amphibians and algae is likely to be low and is not likely to exceed that of the parent compound. In light of these new assumptions, a fish bioconcentration study is no longer a requirement of registration.

4.2 Environmental Risk Characterization

During the original review of pyraflufen-ethyl, the environmental concentrations (EECs) and the risks to the environment were determined using the proposed single application rate of 4.5 g a.i./ha per year. After the conditional registration was granted based on the above use rate, the registrant amended the application rates to up to 9.0 g a.i./ha per year and added additional crops to the label. The environmental risk assessment was revised based on the higher use rate where appropriate, specifically for organisms that were showing an exceedance of the LOC. New risk values and buffer zones were determined for the aquatic species and plants. The updated risk estimates are included in the risk assessment tables in the Appendix (Appendix I, Tables 12, 13 and 14); however, the original EECs and risk quotients (RQs) also remain in the text.

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications (Appendix I, Tables 3, 4 and 5). Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (protection at the community, population, or individual level) (Appendix I, Tables 9, 10 and 11).

Taxonomic group	Exposure	Endpoint	Species Uncertainty Factor
Earthworm	Acute	LC_{50}	0.5
	Chronic	NOEC	1
Other non-target arthropods	Acute	LR_{50}	LOC of 2 (screening level)
Birds	Acute oral	LD_{50}	0.1
	Dietary	LD_{50}	0.1
	Reproduction	NOEL	1
Mammals	Acute oral	LD_{50}	0.1
	Reproduction	NOEL	1
Non-target terrestrial plants	Acute	EC_{25}, or HR_5 of SSD of ER_{50}*	1
Aquatic invertebrates	Acute	LC_{50} or EC_{50}	0.5
	Chronic	NOEC	1
Fish	Acute	LC_{50}	0.1
	Chronic	NOEC	1
Amphibians	Acute	Fish LC_{50}	0.1
	Chronic	Fish NOEC	1
Algae	Acute	EC_{50}	0.5
Aquatic vascular plants	Acute	EC_{50}	0.5

* 5^{th} percentile hazard rate of the species sensitivity distribution of ER_{50} values

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1, except for *T. pyri* and *Aphidius* screening level studies which have an LOC = 2, and bees which have an LOC = 0.4). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

Risk of pyraflufen-ethyl (including the end-use product) to terrestrial organisms was based upon evaluation of toxicity data for the following (Appendix I, Table 12):

- Acute and chronic studies with mammal and bird species representing vertebrates.
- Acute and chronic studies using the technical grade active ingredient for earthworms.

- Acute oral and contact studies using the technical grade active ingredient and end-use product with bees.
- Acute contact studies with beneficial arthropods.
- Seedling emergence and vegetative vigour studies using the end-use product on terrestrial vascular plants.

Terrestrial invertebrates

Soil dwelling arthropods (Earthworms)

Pyraflufen-ethyl is not toxic to earthworms and is not expected to pose a risk.

Bees

Contact exposure: Risk to bees was calculated using results from an acute toxicity test with the TGAI and a separate test with the formulated end-use product (EP) ET-751 2.5% EC. Although the end-use product had adverse effects on bee survival, the level of concern was not exceeded and the RQ was <0.1 (Appendix I, Table 12).

Oral exposure: For the oral exposure route, the TGAI toxicity endpoint was used to determine risk as the EP formulation is not expected to be found in food items. Based on available information, the use of pyraflufen-ethyl is not expected to pose an acute oral or contact risk to bees (Appendix I, Table 12).

Larval bee toxicity: As exposure of bee larvae to the formulated end-use product is not expected due to rapid dissipation from the site of application, toxicity is not a concern. It is unlikely that bees would pick up end-use product material from food and pollen and carry it back to the hive where long term exposure could result.

Predators and parasites: Beneficial insects

Toxicity data available for predatory mites and parasitic wasps indicates both acute and reproductive sensitivity to the end-use product. Based on the empirical toxicity value of LD_{50} <1.6 L end-use product/ha and the application rate of 0.18 L end-use product/ha, risk could not be determined for beneficial insects (RQ > 0.11). The PMRA cannot determine if the LOC is exceeded as the only available study had a single exposure dose which showed significant adverse effects. Therefore, it is assumed that beneficial insects will be adversely affected by the formulated end-use product and appropriate mitigative label statements will be required.

Terrestrial vertebrates

Birds

Birds showed no adverse effects to pyraflufen-ethyl from either acute oral exposure or dietary intake through food. When mallard ducks were exposed chronically through food, significant reproductive effects were noted with a NOAEL of 324 ppm diet. This toxicity endpoint is equivalent to a daily exposure of 18.3 mg a.i./kg bw/d, which, when compared to an EDE of ≤

0.226 a.i./kg bw/d, results in an RQ of < 0.1. Based on the proposed application rate, there is negligible acute and chronic risk to birds from exposure to pyraflufen-ethyl (Appendix I, Table 13).

Mammals

Pyraflufen-ethyl and the formulated end-use product are practically non-toxic to mammals acutely and no risk is expected. Adverse chronic effects were seen in rats in a two generation reproduction study with the TGAI (toxic to adults and offspring at 1000 ppm in the diet); however, no reduction was observed in the production of young at up to 10,000 ppm in the diet. There are negligible acute or chronic risks to small mammals from the use of pyraflufen-ethyl (Appendix I, Table 13).

Terrestrial plants

Non-target Vascular Plants

Plants are sensitive to the formulated end-use product and a potential risk was determined based on an overspray scenario for non-target plants (RQ = 23.7 for plant vigor). Mitigative measures, in the form of buffer zones, will be required to protect non-target terrestrial plants.

A Tier II spray drift assessment was conducted for terrestrial plants and indicated that non-target plants within 1 m of a treated field would be exposed to pyraflufen-ethyl concentrations exceeding the LOC (RQ = 1.4) (Appendix I, Table 12).

4.2.2 Risks to Aquatic Organisms

Risk of pyraflufen-ethyl (including the end-use product and the transformation product E1) to aquatic organisms was based upon evaluation of toxicity data for the following (Appendix I, Table 14):

- Acute and chronic invertebrate study with technical grade active ingredient and transformation product E1
- Acute invertebrate study with the formulated end-use product
- Acute studies using two freshwater fish species (bluegill sunfish, rainbow trout) with the technical grade active ingredient, end-use product and transformation product E1.
- Chronic studies using fathead minnow with the technical grade active ingredient and the transformation product E1. This information was used as a surrogate for the amphibian risk assessment.
- 2 algal species, diatom and a vascular plant (duckweed) with information provided on the end-use product, technical grade active ingredient and transformation product E1.

Risk of pyraflufen-ethyl (including the end-use product) to marine organisms was based upon evaluation of toxicity data for the following (Appendix I, Table 14):

- Acute invertebrate studies with the Eastern oyster and mysid shrimp using the technical grade active ingredient and transformation product E1.

- An acute fish toxicity of the sheepshead minnow using the technical grade active ingredient and the transformation product E1.
- An acute study of marine diatom using the formulated end-use product.

Aquatic organisms could be exposed to pyraflufen-ethyl from drift or runoff. At the screening level, expected environmental concentrations are calculated based on a direct application to water at the maximum cumulative rate, thus taking into account the maximum labelled application rate, the application interval and the dissipation of the compound in aquatic systems. Bodies of water of two depths are considered for the risk assessment. A depth of 15 cm is representative of a seasonal water body used by amphibians during the reproduction period.

A depth of 80 cm is representative of a permanent water body for all other aquatic organisms. The screening level EECs are based on the maximum seasonal application rate of 4.5 g a.i./ha (Appendix I, Table 3). The EECs were determined to be 0.56 µg a.i./L in 80 cm water and 3.0 µg a.i./L in 15 cm water.

Refined aquatic risk assessments were conducted for a spray drift scenario (6% off field deposition rate based on ground boom application with medium droplet size) and a runoff scenario. The EECs for drift were 0.034 µg/L (80 cm water depth) and 0.18 µg a.i./L (15 cm water depth). The EECs used for runoff risk determination were the peak concentration (0.43 µg a.i./L for 80 cm water depth) and the 21 day mean concentration (1.2 µg a.i./L for 15 cm water depth).

Water modelling for runoff was determined using a conservative exposure scenario for the combined residues relevant to the environment (as described in Section 3 of ERC2014-03). With this assessment approach, runoff from the site of application would be expected to result in the exceedance of the LOC for amphibians and freshwater algae from exposure to the parent chemical. However, when exposure to the transformation product E1 is considered, the level of concern is not exceeded. Therefore, although there is uncertainty around the toxicity of the transformation products E2 and E3, the E1 transformation product is most likely to be found in water, and it may be assumed that risk to aquatic organisms from runoff of pyraflufen-ethyl is relatively low. Similarly, when revised application rates of up to 9 g a.i./ha are used, the same results are obtained for amphibians and freshwater algae; that is, the parent chemical produces RQs that exceed the LOC. However, as stated, the parent molecule transforms rapidly to the product E1 which is the major form of pyraflufen-ethyl in soil and water (up to 93%), and the LOC is not exceeded from exposure to E1 for either taxonomic group. In order to reduce runoff into surface waters, label statements are required on the product labels to inform users of the potential risks.

Freshwater invertebrates

At the screening level, the risks of pyraflufen-ethyl and the end-use product to freshwater invertebrates did not exceed the level of concern (RQ < 0.1).

Fish and amphibians

At the screening level, the level of concern was not exceeded for freshwater fish from the use of the technical grade active ingredient, the formulated end-use product or the transformation product E1. A risk was identified at the screening level for amphibians, based on the early life stage study of fathead minnow (RQ=3.4). Refined risk assessments using EEC values for drift and runoff water modelling resulted in RQ values of 0.2 and 1.3, respectively. As the level of concern was exceeded for the refined runoff assessment, amphibians may be at risk from concentrations of pyraflufen-ethyl in runoff water. Mitigation in the form of spray buffer zones will be required and runoff reduction statements will be put on the label.

Freshwater algae and plants

The level of concern was exceeded at the screening level for algae, with an RQ of 3.5. Refined risk assessments using EEC values for drift and runoff water modelling resulted in RQ values of 0.2 and 2.7 respectively. As the level of concern was exceeded for the refined runoff assessment, algae may be at risk from residues of pyraflufen-ethyl in runoff water. Mitigation in the form of spray buffer zones will be required.

Marine organisms

The level of concern was not exceeded for marine invertebrates and fish in a screening level risk assessment using the technical grade active ingredient. The level of concern was not exceeded for marine algae in a screening level risk assessment using the transformation product E1.

5.0 Value

For details on the value review for pyraflufen-ethyl refer to ERC2014-03.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, in other words, persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, pyraflufen-ethyl and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

---

[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

- Pyraflufen-ethyl does not meet Track 1 criteria, and is not considered a Track 1 substance. See Appendix I, Table 15 for comparison with Track 1 criteria.

- Pyraflufen-ethyl does not form any transformation products that meet all Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

> The end-use product Pyro Herbicide does not contain any formulants of health or environmental concern identified in the *Canada Gazette*. However, the end-use product does contain an aromatic petroleum distillate. Therefore, the label for the end-use product Pyro Herbicide will include the statement: **"This product contains aromatic petroleum distillates that are toxic to aquatic organisms."**

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

For additional details please refer to ERC2014-03.

7.1 Human Health and Safety

For details please refer to ERC2014-03.

---

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

7.2 Environmental Risk

Pyraflufen-ethyl, the end-use poduct and its major transformation products are not expected to present a risk to bees, birds and small mammals. However, pyraflufen-ethyl may affect beneficial invertebrates, terrestrial plants, algae, fish and amphibians. In order to mitigate the potential effects of pyraflufen-ethyl to non-target organisms in terrestrial and aquatic habitats, instructions for spray buffer zones and reduction of run-off are required on the label.

7.3 Value

For details please refer to ERC2014-03.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Pyraflufen-ethyl Technical and Pyro Herbicide, containing the technical grade active ingredient pyraflufen-ethyl, to be used for control of emerged broadleaf weeds prior to the emergence of wheat (spring, durum, and winter), barley, oats, rye (spring and fall), triticale, buckwheat, pearl millet, proso millet, canola, mustard, peas, beans, lentils, corn and soybean.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

>	greater than
≥	greater than or equal to
<	less than
≤	less than or equal to
µg	micrograms
AB	Alberta
a.i.	active ingredient
atm	atmosphere
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
CEPA	*Canadian Environmental Protection Act*
cm	centimetres
d	day(s)
DACO	data code
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 90% decline in concentration)
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental concentration
ELS	early life stage
EP	end-use product
ER_{50}	effective rate for 50% of the population
ERC	evaluation report
FIR	food ingestion rate
g	gram
ha	hectare(s)
HD_5	hazardous dose to 5%
HPLC	high performance liquid chromatography
HR_5	hazardous dose to 5% (of species)
hr	hour(s)
kg	kilogram
K_d	soil-water partition coefficient
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
LR_{50}	lethal rate 50%
m	metre
mg	milligram

mL	*millilitre*
MB	Manitoba
MRL	maximum residue limit
MT	moderately toxic
NA	not available/not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
ON	Ontario
Pa	Pascal
PEI	Prince Edward Island
PMRA	Pest Management Regulatory Agency
PNT	practically toxic
ppm	parts per million
QC	Quebec
RNT	relatively non-toxic
RQ	risk quotient
SSD	species sensitivity distribution
ST	slightly toxic
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution
VHT	very highly toxic

Appendix I Tables and Figures

Table 1 Fate and behaviour in the terrestrial environment

Property	Value	Major Transformation products	Comments	PMRA#
Abiotic transformation				
Hydrolysis	DT_{50}: -pH4 = stable -pH7 = 10.8d -pH 9 < 2.4hr	E1; stable to further hydrolysis at all pHs.	Hydrolyses at neutral pH and shows a high potential to hydrolyze at higher pH.	2130063 2268941
Phototransformation in soil	DT_{50} = 2 d	E1 E2	Undergoes phototransformation in soil. Transformation is faster in the dark.	2268953
Biotransformation				
Biotransformation in acrobic soil	DT_{50} Active: < 1d Total Residues*: 326-1630 d (80^{th}% = 557d)	E1 E2 E3	Soil biotransformation is very rapid. Mean half-life for E1 was 14d. E2 and E3 are persistent and may accumulate in soil. Total residues* are persistent in soils and may carry over to the next season.	2268973 2268966 2268961 2130168 2268982 2268985
Biotransformation in anaerobic soil	DT_{50} = 1d	E1 (99%, DT_{50}= 191d) E2 (28%, DT_{50}= 392d)	Rapid degradation in flooded soil. Major transformation products are persistent.	2130171 2130172
Mobility				
Adsorption / desorption in soil	Active K_{oc} = 2000 E1 K_{oc} = 81-197 E2 K_{oc} = 1424-2179 E3 K_{oc} = 3098-4354	-	Mobility: Active: slight E-1: high E-2: low E-3: slight	2268992 2269055 2269058 2269070
Soil leaching	-	-	The active and its major products do not leach below 15 cm depth. leachate: 0.2-0.5%	2269053 2269069
Volatilization	NA	-	Not volatile	-
Field studies				
Field dissipation/ Field leaching	DT_{50}<1d	E1 (DT_{50}= 10.5-161d), E2 E3	Parent dissipates within hours. Residues were not found in soil layers below 15 cm depth.	2130238 2269066
*Total residues is the sum of the parent, E1, E2, E3 and E9 products, as appropriate.				

Table 2 Fate and behaviour in the aquatic environment

Study type	Value	Major Transformation products	Comments	PMRA#
Abiotic transformation				
Hydrolysis	DT_{50}: pH4 = stable pH7 = 10.8d pH 9 < 2.4hr	E1 (stable to further hydrolysis at all pHs).	Hydrolyses at neutral pH and shows a high potential to hydrolyze at higher pH.	2130063, 2268941
Phototransformation in water	DT_{50}= 5d (12hr cycle)	Possibly PD-1 (one label only)	Active photolyzes in water.	2269071, 2269075
Biotransformation				
Biotransformation in aerobic water systems	Active: DT_{50}/ $DT_{90water}$= <6hr DT_{50}/ $DT_{90system}$= <6hr Total Residues*: $DT_{50system}$= 274-436d	E1 E2	Rapid degradation occurs in water/sediment systems. E1 mainly found in water but also in sediment, E2 is persistent, only found in sediment. Total residues* are persistent in the system.	2268990
Biotransformation in anaerobic water systems	Active: DT_{50}/ $DT_{90water}$= <4hr DT_{50}/ $DT_{90system}$= <4hr Total Residues*: $DT_{50system}$= 2088d	E1 E2	Rapid degradation of active occurs in water/sediment systems. E2 is persistent and accumulates in the sediment. Total residues are persistent in the system.	2268987
Partitioning				
Adsorption / desorption in sediment	-	-	Major products : E1 can partition to sediment to some extent, mostly found in water, E2 is only found in sediment. Minor product E3 accumulates in sediment.	2268990 2268987
Bioconcentration	18X	-	The major transformation product E1 has a low potential for bioconcentration	2269067
Field studies				
Field dissipation	NA			

*Total residues is the sum of the parent, E1, E2, E3 and E9 products, as sppropriate. NA: Not available.

Table 3 EECs in soil and water*

Compartment		TGAI		E1 (transformation product)	
		EEC	Drift (6%) EEC		
Soil		0.002 mg /kg	1.2E-4 mg /kg	-	-
Water	80 cm	0.56 µg/L	0.034 µg/L	0.52 µg /L	0.03 µg/L
	15 cm	3 µg/L	0.18 µg/L	2.8 µg/L	0.17 µg/L
Runoff	80 cm	Peak: 0.43 µg/L 21d: 0.41 µg/L	-	Peak: 0.4 µg/L 21d: 0.41 µg/L	-
	15 cm	Peak: 1.7 µg/L 21d: 1.2 µg/L	-	Peak: 1.6 µg/L 21d: 1.1 µg/L	-

*Application of pyraflufen-ethyl at 1 × 4.5g a.i./ha.

Table 4 **Level 1 aquatic ecoscenario modelling EECs (µg a.i./L) for pyraflufen-ethyl combined residue in a water body 0.8 m deep, excluding spray drift**

Region-crop	EEC (µg a.i./L)					
	Peak	96-hr	21-day	60-day	90-day	Yearly
BC-wheat	0.093	0.091	0.087	0.087	0.087	0.067
BC-corn	0.010	0.010	0.009	0.008	0.007	0.004
Prairie-wheat	0.11	0.10	0.10	0.093	0.089	0.070
Prairie-corn and soybeans	0.21	0.21	0.19	0.18	0.17	0.14
ON-corn and soybeans	0.21	0.21	0.20	0.18	0.17	0.11
QC-corn and soybeans	0.24	0.23	0.22	0.21	0.20	0.15
Atlantic-wheat, corn and soybeans	0.43	0.43	0.41	0.38	0.35	0.24
Max	0.43	0.43	0.41	0.38	0.35	0.24

Table 5 **Level 1 aquatic ecoscenario modelling EECs (µg a.i./L) for pyraflufen-ethyl combined residue in a water body 0.15 m deep, excluding spray drift**

Region-crop	EEC (µg a.i./L)					
	Peak	96-hr	21-day	60-day	90-day	Yearly
BC-wheat	0.34	0.31	0.24	0.17	0.15	0.068
BC-corn	0.041	0.037	0.026	0.017	0.014	0.005
Prairie-wheat	0.39	0.35	0.26	0.19	0.17	0.081
Prairie-corn and soybeans	0.74	0.68	0.50	0.35	0.30	0.15
ON-corn and soybeans	0.75	0.67	0.56	0.41	0.35	0.15
QC-corn and soybeans	0.85	0.80	0.62	0.42	0.35	0.15
Atlantic-wheat, corn and soybeans	1.7	1.6	1.2	0.83	0.70	0.30
Max	1.7	1.6	1.2	0.83	0.70	0.30

Table 6 **Revised Level 1 aquatic ecoscenario modelling EECs for pyraflufen-ethyl combined residue in a water body 0.8 m deep, excluding spray drift. Based on new maximum application rate of 9 g a.i./ha**

Region/Scenario	EEC (µg a.i./L)					
	Peak	96-hr	21-day	60-day	90-day	Yearly
BC/Barley-AB	0.16	0.16	0.15	0.14	0.13	0.097
Prairie/Wheat-MB	0.49	0.49	0.48	0.44	0.41	0.25
On/Corn-ON	0.41	0.41	0.40	0.42	0.39	0.25

Region/Scenario	EEC (µg a.i./L)					
	Peak	96-hr	21-day	60-day	90-day	Yearly
Qc/Corn-QC	0.68	0.67	0.65	0.59	0.56	0.41
Atlantic/Potato-PEI	0.87	0.87	0.84	0.78	0.73	0.45
Max	0.87	0.87	0.84	0.78	0.73	0.45

Table 7 Revised Level 1 aquatic ecoscenario modelling EECs for pyraflufen-ethyl combined residue in a water body 0.15 m deep, excluding spray drift. Based on new maximum application rate of 9 g a.i./ha

Region/Scenario	EEC (µg a.i./L)					
	Peak	96-hr	21-day	60-day	90-day	Yearly
BC/Barley-AB	0.58	0.55	0.43	0.30	0.24	0.10
Prairie/Wheat-MB	1.8	1.8	1.6	1.1	0.91	0.40
On/Corn-ON	1.7	1.6	1.2	0.96	0.83	0.33
Qc/Corn-QC	2.6	2.4	2.1	1.4	1.2	0.54
Atlantic/Potato-PEI	3.7	3.5	2.9	1.9	1.6	0.60
Max	3.7	3.5	2.9	1.9	1.6	0.60

Table 8 Major groundwater and surface water model inputs for Level 1 assessment of pyraflufen-ethyl and its major transformation products E1, E2, E3 and E9

Type of Input	Parameter	Value
Application Information	Crop(s) to be treated	Spring wheat, field corn and soybeans
	Maximum allowable application rate per year (g a.i./ha)	4.5
	Maximum rate each application (g a.i./ha)	4.5
	Maximum number of applications per year	1
	Minimum interval between applications (days)	NA
	Method of application	Ground foliar to weeds only, no direct contact to crops
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 (days)	Stable for the combined residue modelling
	Photolysis half-life in water (days)	5 for the combined residue
	Adsorption K_d (mL/g)	2.27 (20^{th} percentile of three K_d values of E1) for the combined residue modelling
	Aerobic soil biotransformation half-life (days)	673 (90^{th} percentile confidence bound on mean of six half-life values adjusted to 25°C) for the combined residue modelling
	Aerobic aquatic biotransformation half-life (days)	436 (longest of two half-lives) for the combined residue modelling
	Anaerobic aquatic biotransformation half-life (days)	2088 (the only half-life

Type of Input	Parameter	Value
		available) for the combined residue modelling

Table 9 Toxicity of pyraflufen-ethyl and its end-use product to terrestrial organisms

Organism	Test substance	Exposure	Toxicity Endpoint	Degree of toxicity[a]	Corrected Toxicity Endpoint [b]	PMRA#
Invertebrates						
Earthworm	TGAI	14d-Acute	LC_{50} >1000 mg/kg	-	LC_{50} >500 mg/kg	2130067 2130181
	TGAI	2 month	NOEC > 500 mg a.i./kg	-	NOEC > 500 mg a.i./kg	2130184
Bee	TGAI	48h-Oral	LC_{50} >112 µg a.i./bee	RNT[4]	LC_{50} >112 µg a.i./bee	2269553
		48h-Contact	LC_{50} >100 µg a.i./bee	RNT	LC_{50} >100 µg a.i./bee	2130182
	EP	96h-Oral	LD50 < 4.27 µg a.i./bee	MT[3]	LD50 < 4.27 µg a.i./bee	2130313
		96h-Contact	LD50 = 9.82 µg a.i./bee (392.8 µg EP/bee)	RNT[3]	LD50 = 9.82 µg a.i./bee (392.8 µg EP/bee)	
Predatory arthropod, mite	EP	7d-Contact	LR_{50} < 1.6L/ha NOEC < 1.6L/ha	-	LR_{50} < 1.6L/ha NOEC < 1.6L/ha	2222195
Parasitic arthropod, wasp	EP	24h-Contact	LR_{50} < 1.6L/ha NOEC < 1.6L/ha	-	LR_{50} < 1.6L/ha NOEC < 1.6L/ha	2222197
Birds						
Bobwhite quail	TGAI	15d-Acute	LD50> 2000 mg/kg bw	PNT[2]	LD50> 200 mg/kg bw	2269565
	TGAI	8d-Dietary	LC_{50}: >5000 ppm (>1085 mg/kg bw) NOEC: 5000 ppm (1085 mg/kg bw)	PNT	LC_{50}: >500 ppm (>108.5 mg/kg bw) NOEC: 500 ppm (108.5 mg/kg bw)	2269560
	TGAI	Reproduction	NOAEC: 4836 mg/kg dw; LOAEC: >4836 mg/kg dw (513.4 mg/kg bw)	-	NOAEC: 4836 mg/kg dw; LOAEC: >4836 mg/kg dw (513.4 mg/kg bw)	2269514
Mallard duck	TGAI	Acute	-	-	-	-
		8d-Dietary	LC_{50}: >5000 ppm (> 1572 mg/kg bw) NOEC: 5000 ppm (1572 mg/kg bw)	PNT	LC_{50}: >500 ppm (> 157.2 mg/kg bw) NOEC: 500 ppm (157.2 mg/kg bw)	2269564
		Reproduction	NOAEC: 324 mg/kg dw (18.3 mg/kg bw) LOAEC: 3240 mg/kg dw	-	NOAEC: 324 mg/kg dw (18.3 mg/kg bw) LOAEC: 3240 mg/kg dw	2269533
Mammals						
Rat	TGAI	96hr Acute	LD_{50} >5000 mg/kg bw	PNT	LD_{50} >500 mg/kg bw	HED Tox table.
	EP	96 hr Acute	LD_{50} = 3712 mg/kg bw (females)	PNT	LD_{50} = 371.2 mg/kg bw (females)	
	TGAI	Reproduction	NOAEL = 1000 ppm diet; (70.8 mg/kg bw (males)) Pup wt.	-	NOAEL = 1000 ppm diet; (70.8 mg/kg bw (males)) Pup wt.	
Mouse	TGAI	96hr Acute	LD_{50} >5000 mg/kg bw	PNT	-	
Vascular plants						
Terrestrial Vascular plants	EP	14d-Seedling emergence	EC_{25} = 1.3 g a.i./ha	-	EC_{25} = 1.3 g a.i./ha	2269535 2130205
	EP	24d-Vegetative vigour	HD_5 = 0.19 g a.i./ha (SSD based on EC50[1])	-	HD_5 = 0.19 g a.i./ha (SSD based on EC50[1])	2269536 2130204
	EP	14d-Vegetative	EC_{25} = 2.69 g a.i./ha	-	EC_{25} = 2.69 g a.i./ha	2269519 2130203

		vigour				

[a] Atkins et al. (1981) for bees and USEPA classification for others, where applicable. [b] Corrected endpoint is used in the risk assessment, see Table 11 for uncertainty factors applied; [1] SSD is based on EC50 for cucumber lettuce, turnip, tomato, onion, and soybean, 0.55, 0.33, 0.46, 0.45, 2.1, 1.2 g a.i./ha, respectively.[2] PNT: Practically non-toxic; [3]MT: Moderately toxic; [4]RNT: Relatively non-toxic; [5] The EP is contributing to toxicity, thus this endpoint is considered RNT.

Table 10 Toxicity of pyraflufen-ethyl, its end-use product and the major transformation product E1 to aquatic organisms

Organism	Test substance	Exposure	Toxicity Endpoint	Degree of toxicity[a]	Corrected Toxicity Endpoint [b]	PMRA#
Freshwater species						
Invertebrates						
Water flea, *Daphnia sp.*	TGAI	48h-Acute	EC_{50} >82 µg a.i./L	VHT[4]	EC_{50} >41 µg a.i./L	2269568
	TGAI	21d-Chronic	NOEC = 81 µg a.i./L reproduction	-	NOEC = 81 µg a.i./L reproduction	2269578
	EP[1]	48h-Acute	EC_{50} = 20 µg a.i./L (760 µg EP/L)	VHT	EC_{50} = 10 µg a.i./L (380 µg EP/L)	2269521
	E1[2]	48h-Acute	EC_{50} > 121 mg/L	PNT[5]	EC_{50} > 60.5 mg/L	2269608
	E1	21d-Chronic	NOEC = 99mg/L (# offspring)	-	NOEC = 99mg/L (# offspring)	2269538
Midge, *Chironomus sp.*	TGAI	21d-Chronic	NOEC ≥ 54 µg a.i./L, emergence	-	NOEC ≥ 54 µg a.i./L, emergence	2269622
Fish/amphibians						
Rainbow trout *Onchorhincus sp.*	TGAI	96h-Acute	LC_{50} > 101 µg a.i./L	VHT[a]	LC_{50} > 10.1 µg a.i./L	2269583
	EP (2% SC)	96h-Acute	LC_{50} > 2520 µg a.i./L (>126 mg EP/L)	PNT	LC_{50} > 252 µg a.i./L (>12.6 mg EP/L)	2269619
	E1	96h-Acute	LC_{50} > 118 mg/L	PNT	LC_{50} > 11.8 mg/L	2269537
Bluegill sunfish *Lepomis sp.*	TGAI	96h-Acute	LC_{50} > 85 µg a.i./L	VHT[a]	LC_{50} > 8.5 µg a.i./L	2130191
	EP	96h-Acute	EC_{50} = 86 µg a.i./L (3.3 mg EP/L)	VHT	EC_{50} = 8.6 µg a.i./L (0.33 mg EP/L)	2269526
	E1	96h-Acute	EC_{50} > 90 mg/L	ST[5]	EC_{50} > 9.0 mg/L	2269525
Fathead minnow *Pimephales sp.*	TGAI	28d ELS	NOEC: 3.4 µg a.i./L, growth	-	NOEC: 3.4 µg a.i./L, growth	2269576
	TGAI	28d ELS (High UV)	NOEC: 0.89 µg a.i./L, growth	-	NOEC: 0.89 µg a.i./L, growth	2269637 2269639
	E1	28d ELS	LC_{50} >10 mg/L NOEC: 10 mg/L	-	LC_{50} >1.0 mg/L NOEC: 10 mg/L	2269550
Amphibians[c]	EP	96h-Acute	EC_{50} = 86 µg a.i./L (3.3 mg EP/L)	VHT	EC_{50} = 8.6 µg a.i./L (0.33 mg EP/L)	2269526
	TGAI	28d ELS (High UV)	NOEC: 0.89 µg a.i./L, growth	-	NOEC: 0.89 µg a.i./L, growth	2269637 2269639
	E1	28d ELS	LC_{50} >10 mg/L NOEC: 10 mg/L	-	LC_{50} >1.0 mg/L NOEC: 10 mg/L	2269550
Freshwater alga						
Green alga, *Anabaena sp.*	EP	96hr-Acute	EC_{50} = 34 µg a.i./L	-	EC_{50} = 17 µg a.i./L	2269592 2222199
Green alga *Pseudokirch./ Selenastrum sp.*[d]	EP	96hr-Acute	EC_{50} = 2.6 µg a.i./L	-	EC_{50} = 1.3 µg a.i./L	2269598 2222200
	TGAI	72hr-Acute	EC_{50} = 0.31 µg a.i./L	-	EC_{50} = 0.16 µg a.i./L	2130201
	E1	72hr-Acute	EC_{50} = 2.2 µg /L	-	EC_{50} = 1.1 µg /L	2130202
Diatom *Navicula sp.*	EP	96hr-Acute	EC_{50} = 1.5 µg a.i./L	-	EC_{50} = 0.75 µg a.i./L	2269602
	TGAI	72hr-Acute	EC_{50} = 1.6 µg a.i./L	-	EC_{50} = 0.76 µg a.i./L	2130197
	E1	72hr-Acute	EC_{50} = 1700 µg/L	-	EC_{50} = 850 µg/L	2130198
Vascular plant						
Duck weed *Lemna sp.*	EP	7d	EC_{50} = 16 µg a.i./L	-	EC_{50} = 8 µg a.i./L	2269595 2222203
	E1	7d	EC_{50} = 2.6 µg /L	-	EC_{50} = 1.3 µg /L	2130206
Marine species						
Invertebrates						
Eastern Oyster	E1	96h-Acute	EC_{50} > 67,000 µg/L	ST	EC_{50} > 33,500 µg/L	2269539
	TGAI	96h-Acute	EC_{50} > 43 µg a.i./L	VHT[a]	EC_{50} > 21.5 µg a.i./L	2269610

Mysid shrimp	E1	96h-Acute	LC_{50} = 9.4 mg/L	MT[6]	LC_{50} = 4.7 mg/L	2269549
Fish						
Sheepshead minnow	TGAI	96h-Acute	LC_{50} > 56 µg a.i./L	VHT[4]	LC_{50} > 5.6 µg a.i./L	2269566
	E1	96h-Acute	LC_{50} > 99 mg /L	PNT	LC_{50} > 9.9 mg /L	2269544
Algae						
Diatom *Skeletonema sp.*	EP	96h-Acute	LC_{50} = 10 µg a.i./L	-	LC_{50} = 5 µg a.i./L	2269601 2222201

[a] USEPA classification, where applicable, [b] Corrected endpoint is used in the risk assessment, see Table 11 for uncertainty factors applied; NOEC values are not corrected; [c] Based on fish ELS study; [d] *Pseudokirchnieriella sp.* is the same as *Selenastrum sp.*, that is, formerly known as *Selenastrum sp.* [1] EP: End-use product ET-751 2.5% EC, [2]E1 – major transformation product; [3] PNT: Practically non-toxic; [4] VHT: Very highly toxic; [5] ST: Slightly toxic; [6] MT: Moderately toxic; [*] This endpoint is a "greater than" value limited to the maximum solubility of the active and does not represent true toxic effects

Table 11 Endpoints used in the risk assessment

Organism	Test substance	Exposure	Toxicity Endpoint	Corrected Toxicity Endpoint[1]	Uncertainty factor applied[2]
Terrestrial organisms					
Earthworm	TGAI[3]	14d-Acute	LC_{50} >1000 mg/kg	LC_{50} >500 mg/kg	2
Bee	TGAI	48 hr-Oral	LC_{50} >112 µg a.i./bee	LC_{50} >112 µg a.i./bee	1
Bee	EP[3]	96h-Contact	LD_{50} = 9.82 µg a.i./bee (392.8 µg EP/bee)	LD_{50} = 9.82 µg a.i./bee (392.8 µg EP/bee)	1
Beneficial Insects (Parasitic wasp)	EP	7d-Contact	LR_{50} < 1.6L/ha NOEC < 1.6L/ha	LR_{50} < 1.6L/ha NOEC < 1.6L/ha	1
Birds (Bobwhite quail/Mallard duck)	TGAI	15d-Acute	LD_{50}> 2000 mg/kg bw	LD_{50}> 200 mg/kg bw	10
		8d-Dietary	LC_{50}: >5000 ppm (>1085 mg/kg bw) NOEC: 5000 ppm (1085 mg/kg bw)	LC_{50}: >500 ppm (>108.5 mg/kg bw) NOEC: 500 ppm (108.5 mg/kg bw)	10
		Reproduction	NOAEC: 4836 mg/kg dw; LOAEC: >4836 mg/kg dw (513.4 mg/kg bw)	NOAEC: 4836 mg/kg dw; LOAEC: >4836 mg/kg dw (513.4 mg/kg bw)	1
Mammals (Rat)	EP	96hr Acute	LD_{50} = 3712 mg/kg bw (females)	LD_{50} = 371.2 mg/kg bw (females)	10
	TGAI	Reproduction	NOAEL = 1000 ppm diet; (70.8 mg/kg bw (males)) Pup wt.	NOAEL = 1000 ppm diet; (70.8 mg/kg bw (males)) Pup wt.	1
Terrestrial vascular plants	EP	Vegetative vigour	HD_5 = 0.19 g a.i./ha (SSD based on EC_{50})	HD_5 = 0.19 g a.i./ha (SSD based on EC_{50})	1
Aquatic organisms					
Freshwater invertebrates (*Daphnia sp*)	EP	48h-Acute	EC_{50} = 20 µg a.i./L (760 µg EP/L)	EC_{50} = 10 µg a.i./L (380 µg EP/L)	2
	TGAI	21d-Chronic	NOEC = 81 µg a.i./L reproduction	NOEC = 81 µg a.i./L reproduction	1
Midge, *Chironomus sp.*	TGAI	21d-Chronic	NOEC ≥ 54 µg a.i./L, emergence	NOEC ≥ 54 µg a.i./L, emergence	1
Freshwater fish (Bluegill sunfish)	EP	96h-Acute	EC_{50} = 86 µg a.i./L (3.3 mg EP/L)	EC_{50} = 8.6 µg a.i./L (0.33 mg EP/L)	10
Freshwater fish (Fathead minnow)	TGAI	28d ELS	NOEC: 3.4 µg a.i./L, growth NOEC: 0.89 µg a.i./L, growth (High UV light)	NOEC: 3.4 µg a.i./L, growth NOEC: 0.89 µg a.i./L, growth (High UV light)	1
Freshwater fish (Fathead minnow)	E1	28d ELS	NOEC: 10 mg/L	NOEC: 10 mg/L	1
Amphibians (based on fish acute EC_{50} and ELS NOEC)	EP	96h-Acute	EC_{50} = 86 µg a.i./L (3.3 mg EP/L)	EC_{50} = 8.6 µg a.i./L (0.33 mg EP/L)	10
	TGAI	28d ELS	NOEC: 0.89 µg a.i./L, growth (High UV light)	NOEC: 0.89 µg a.i./L, growth (High UV light)	1
	E1	28d ELS	NOEC: 10 mg/L	NOEC: 10 mg/L	1
Aquatic vascular plants (*Lemna*)	E1	7d	EC_{50} = 2.6 µg a.i./L	EC_{50} = 1.3 µg a.i./L	2

Algae (*Selenastrum*)	TGAI	72hr-Acute	EC_{50} = 0.31 µg a.i./L	EC_{50} = 0.16 µg a.i./L	2
	E1	72hr-Acute	EC_{50} = 2.2 µg /L	EC_{50} = 1.1 µg /L	
Saltwater invertebrates (oyster)	TGAI	96h-Acute	EC_{50} > 43 µg a.i./L	EC_{50} > 21.5 µg a.i./L	2
Saltwater fish (sheepshead minnow)	TGAI	96h-Acute	LC_{50} > 56ug a.i./L	LC_{50} > 5.6 µg a.i./L	10
Saltwater algae (*Skeletonema*)	EP	96h-Acute	EC_{50} = 10 µg a.i./L	EC_{50} = 5 µg a.i./L	2

[1] Corrected values are derived using the uncertainty factors in this table; [2] According to PMRA guidance; [3] TGAI: technical grade active ingredient; [4]EP: end-use product.

Table 12 Risk to terrestrial invertebrates and plants

Organism	Exposure	Test Substance	Endpoint value	EEC[2]	RQ[3]	Risk LOC[4] Exceeded
Screening Level Risk Assessment: Overspray at 4.5g a.i./ha × 1						
Invertebrates						
Earthworm	Acute	TGAI	LC_{50} >500 mg/kg	0.002 mg a.i./kg	<<1	NO
Bee[5]	Oral	TGAI	LC_{50} >112 µg a.i./bee	0.13 µg a.i./bee	<0.1	NO
	Contact	EP	LC_{50} = 9.82 µg a.i./bee 392.8 µg EP/bee	0.01 µg a.i./bee 0.43 µg EP/bee	<0.1	NO
	Brood / hive	NA	NA	NA	NA	NA
Predatory arthropod	Contact	EP	LR_{50} < 1.6L/ha	0.18L/ha	>0.11	NA
Parasitic arthropod	Contact	EP	LR_{50} < 1.6L/ha	0.18L/ha	>0.11	NA
Vascular plants						
Vascular plants	Vegetative vigour	EP	HD_5 = 0.19 g a.i./ha (SSD based on EC_{50})	4.5 g a.i./ha	**23.7**	**YES**
	14d-Seedling emergence	EP	EC_{25} = 1.3 g a.i./ha	4.5 g a.i./ha	**3.46**	**YES**
Refined Risk Assessment: Spray Drift						
Vascular plants	Vegetative vigour	EP	HD_5 = 0.19 g a.i./ha	6% Drift[1]		
				0.27 g a.i./ha	**1.42**	**YES**
	14d-Seedling emergence	EP	EC_{25} = 1.3 g a.i./ha	0.27 g a.i./ha	0.2	NO

Revised[*] Screening Assessment, Overspray at 9g a.i./ha × 1						
Vascular plants						
Vascular plants	Vegetative vigour	EP	HD_5 = 0.19 g a.i./ha (SSD based on EC_{50})	9 g a.i./ha	**47.4**	**YES**
	14d-Seedling emergence	EP	EC_{25} = 1.3 g a.i./ha	9 g a.i./ha	**6.92**	**YES**
Refined Risk Assessment: Spray Drift						
Vascular plants	Vegetative vigour	EP	HD_5 = 0.19 g a.i./ha	6% Drift[1]		
				0.54 g a.i./ha	**2.84**	**YES**

[1] Drift at 1m distance from site of application is 6% of applied rate using a ground boom and medium droplet size.
[2] Estimated Environmental Concentration (EEC),
[3] Risk Quotient (RQ) = exposure/toxicity;
[4] Level of Concern (LOC), bolded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment using drift; NA: Not available/applicable;
[5] EECs for bees: TGAI: Contact exposure EEC= (2.4 µg a.i./bee per kg/ha) × (0.0045 kg a.i./ha) = 0.01 µg a.i./bee; EP: Contact exposure EEC= (2.4 µg EP/bee per kg/ha) × (0.18 kg EP/ha) = 0.43 µg EP/bee; TGAI: Oral exposure EEC= (29 µg a.i./bee per kg/ha) × (0.0045 kg a.i./h) = 0.13 µg a.i./bee. The oral exposure estimate for adult bees is calculated by multiplying the direct single rate by 29 µg a.i./bee per kg/ha. This conversion is based on consumption rates primarily derived from Rortais et al. (2005,

refer to ERC2014-03, *Pyraflufen*) and Crailsheim et al. (1992 and 1993; refer to ERC2014-03). For the contact exposure estimate for bees, a conversion from kg a.i./ha to µg a.i./bee was required. The proposed upper-bound residue value for estimating exposure to bees is based on the maximum residue value reported by Koch and Weißer (1997; refer to ERC2014-03); 2.4 µg a.i./bee per kg/ha.

Table 13 Risk to birds and mammals (Screening assessment; overspray at 4.5g a.i./ha × 1)

Birds					
Size	**Food type**	**Endpoint**	**Toxicity[1] (mg a.i./kg bw/d)**	**EDE[3] (mg a.i./kg bw)**	**RQ[2]**
Small	Small insects	Acute	200	0.226	<0.1
		Reproduction	18.3	0.226	<0.1
Medium	Small insects	Acute	200	0.177	<0.1
		Reproduction	18.3	0.177	<0.1
Large	Short grass	Acute	200	0.185	<0.1
		Reproduction	18.3	0.185	<0.1
Mammals					
Size	**Food type**	**Endpoint**	**Toxicity (mg a.i./kg bw/d)**	**EDE (mg a.i./kg bw)**	**RQ**
Small	Small insects	Acute	371	0.129	<0.1
		Reproduction	70.8	0.129	<0.1
Medium	Short grass	Acute	371	0.397	<0.1
		Reproduction	70.8	0.397	<0.1
Large	Short grass	Acute	371	0.218	<0.1
		Reproduction	70.8	0.218	<0.1

[1] Endpoints were divided by an uncertainty factor to account for varying protection goals (that is, protection at the community, population, or individual level)

[2] RQ = exposure/toxicity; RQs < 0.1 were not calculated to show all decimal points. RQs are based on estimated environmental concentrations (EEC): For birds and mammals, the EEC takes into account the maximum seasonal cumulative rate on vegetation and is calculated using PMRA standard methods based on the Hoerger and Kenaga nomogram as modified by Fletcher (1994)

[3] EDE = Estimated dietary exposure; calculated for each bird or mammal size based on the EEC on appropriate food item for each food guild (at the screening level, the most conservative EEC for each food guild was used). The EDE was calculated using the following formula: (FIR/bw) × EEC. For each body weight (bw), the food ingestion rate (FIR) was based on equations from Nagy (1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used; for mammals, the "all mammals" equation was used:

Passerine Equation (body weight ≤200 g): FIR (g dry weight/day) = $0.398(\text{bw in g})^{0.850}$

All Birds Equation (body weight > 200 g): FIR (g dry weight/day) = $0.648(\text{bw in g})^{0.651}$

All Mammals Equation: FIR (g dry weight/day) = $0.235(\text{bw in g})^{0.822}$

Conversion from a concentration (EEC) to a dose (EDE): [EDE (mg a.i./kg bw) = EEC (mg a.i./kg diet)/bw (g) × FIR (g et/day)] Nagy, K.A. 1987. Field metabolic rate and food requirement scaling in mammals and birds. Ecological Monographs 57:111-128

Table 14 Risk to aquatic organisms from pyraflufen-ethyl herbicide

Organism	**Test substance**	**Exposure**	**Corrected Toxicity Endpoint[2]**	**EEC**	**RQ**	**LOC Exceeded?**
Screening Assessment (overspray at 4.5 g a.i./ha × 1)						
Freshwater species						
Freshwater invertebrates (Daphnia sp)	EP[3]	48h-Acute	EC_{50} = 10 µg a.i./L (380 µg EP/L)	0.56 µg a.i./L (E1: 0.52 µg/L)	<0.1	NO
	TGAI[4]	21d-Chronic	NOEC = 81 µg a.i./L, reproduction		<0.1	
Midge, *Chironomus sp.*	TGAI	21d-Chronic	NOEC ≥ 54 µg a.i./L, emergence		<0.1	
Freshwater fish (Bluegill sunfish)	EP	96h-Acute	EC_{50} = 8.6 µg a.i./L (0.33 mg EP/L)		<0.1	
Freshwater fish (fathead minnow)	TGAI	28d ELS (High UV)	NOEC: 0.89 µg a.i./L, growth		0.63	

	E1	28d ELS	NOEC: 10 mg/L		<0.1	
Amphibians (based on fish acute and ELS study)	EP	96h-Acute	EC_{50} = 8.6 µg a.i./L (0.33 mg EP/L)	3.0 µg a.i./L (E1: 2.8 µg/L)	0.34	
	TGAI	28d ELS	NOEC: 3.4 µg a.i./L, growth		0.88	
			NOEC: 0.89 µg a.i./L, growth (High UV light)		**3.4**	**YES**
	E1	28d ELS	NOEC: 10 mg/L		<0.1	NO
Aquatic vascular plants (Lemna)	E1	7d	EC_{50} = 1.3 µg a.i./L	0.56 µg a.i./L (E1: 0.52 µg/L)	0.4	NO
Algae (Selenastrum)	TGAI	72hr-Acute	EC_{50} = 0.16 µg a.i./L		**3.5**	**YES**
	E1	72hr-Acute	EC_{50} = 1.1 µg /L		0.47	NO
Marine species						
Saltwater invertebrates (oyster)	TGAI	96h-Acute	EC_{50} > 21.5 µg a.i./L	0.56 µg a.i./L	<0.1	NO
Saltwater fish (sheepshead minnow)	TGAI	96h-Acute	LC_{50} > 5.6 µg a.i./L		<0.1	
Saltwater algae (Skeletonema)	EP	96h-Acute	EC_{50} = 5 µg a.i./L		0.11	
Tier I Refined Drift Assessment: 6% drift from groundboom application						
Amphibians	TGAI	28d ELS	NOEC: 0.89 µg a.i./L, growth (High UV light)	0.18 µg a.i./L (E1: 0.17 µg/L)	0.2	NO
	E1	28d ELS	NOEC: 10 mg/L		<0.1	NO
Algae (Selenastrum)	TGAI	72hr-Acute	EC_{50} = 0.16 µg a.i./L	0.034 µg a.i./L	0.2	NO
Tier I Refined Assessment for Runoff:						
Amphibians	TGAI	28d ELS	NOEC: 0.89 µg a.i./L, growth (High UV light)	1.2 µg a.i./L (E1: 1.1 µg/L)	**1.3**	**YES**
	E1	28d ELS	NOEC: 10 mg/L		<0.1	NO
Algae (Selenastrum)	TGAI	72hr-Acute	EC_{50} = 0.16 µg a.i./L	0.43 µg a.i./L (E1: 0.4ug/L)	**2.7**	**YES**
	E1	72hr-Acute	EC_{50} = 1.1 µg /L		0.36	NO

[1]E1: major transformation product; [2]Corrected values are derived using the uncertainty factors in Table 11; [3] EP: end-use product; [4] TGAI: technical grade active ingredient, for runoff EECs TGAI represent the combined residues of concern of parent + E1+E2+E3+E9.

Revised* Screening Assessment (9g a.i./ha × 1):						
Freshwater fish (fathead minnow)	TGAI	28d ELS (High UV)	NOEC: 0.89 µg a.i./L, growth	1.12 µg a.i./L E1: 1.04 µg/L	**1.26**	**YES**
	E1	28d ELS	NOEC: 10 mg/L		<0.2	NO
Amphibians	TGAI	28d ELS	NOEC: 0.89 µg a.i./L, growth (High UV light)	6.0 µg a.i./L (E1: 5.6 µg/L)	**6.7**	**YES**
	E1	28d ELS	NOEC: 10 mg/L		<0.1	NO
Algae (Selenastrum)	TGAI	72hr-Acute	EC_{50} = 0.16 µg a.i./L	1.12 µg a.i./L E1: 1.04 µg/L	**7.0**	**YES**
	E1	72hr-Acute	EC_{50} = 1.1 µg /L		0.9	NO
Revised* Tier I Refined Assessment for Runoff (9g a.i./ha × 1):						
Freshwater fish (fathead minnow)	TGAI	28d ELS (High UV)	NOEC: 0.89 µg a.i./L, growth	0.87 µg a.i./L (E1: 0.8ug/L)	0.98	NO
	E1	28d ELS	NOEC: 10 mg/L		<0.1	NO
Amphibians	TGAI	28d ELS	NOEC: 0.89 µg a.i./L, growth (High UV light)	3.7 µg a.i./L (E1: 3.44 µg/L)	**3.9**	**YES**
	E1	28d ELS	NOEC: 10 mg/L		<0.1	NO
Algae (Selenastrum)	TGAI	72hr-Acute	EC_{50} = 0.16 µg a.i./L	0.87 µg a.i./L (E1: 0.8ug/L)	**5.4**	**YES**
	E1	72hr-Acute	EC_{50} = 1.1 µg /L		0.72	NO

*Revised: This represents the doubling of the original application rate due to the registrant's amendment by a Category B submission for Pyro herbicide after the initial registration at 4.5 g a.i./ha. [1]E1: major transformation product; [2]Corrected values are derived using the uncertainty factors in Table 11; [3] EP: end-use product; [4] TGAI: technical grade active ingredient, for runoff EECs TGAI represent the combined residues of concern of parent + E1+E2+E3+E9.

Table 15 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints	Transformation Products Endpoints
Toxic or toxic equivalent according to the *Canadian Environmental Protection Act*[1]	Yes		Yes	Yes
Predominantly anthropogenic[2]	Yes		Yes	Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	Half-life: <1d	E1:22d E2: 7.7-10.3d E3:154-495d
	Water	Half-life ≥ 182 days	Half-life: <1d	E1: approximately 59 d in whole system
	Sediment	Half-life ≥ 365 days	Half-life: <1d	NA
	Air	Half-life ≥ 2 days or evidence of long range transport	Half-life or volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (4.3E-9 Pa at 20°C) and Henry's Law Constant (7.95E-10 atm m3/mole).	NA
Bioaccumulation[4]	Log K_{OW} ≥ 5		3.4	E3: 3.66 E1 and E2: < 3
	BCF ≥ 5000		18	NA
	BAF ≥ 5000		NA	NA
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.

[1]All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (in other words, all other TSMP criteria are met).
[2]The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.
[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.
[4]Field data (for example, bioaccumulation factors [BAFs]) are preferred over laboratory data (for example, bioconcentration factors [BCFs]) which, in turn, are preferred over chemical properties (for example, *n*-octanol–water partition coefficient [log K_{OW}]).

References

The relevant test data on which the proposed decision is based is referenced below and in ERC2014-03, *Pyraflufen-ethyl*.

A. List of Studies/Information Submitted by Registrant

1.0 Environment

PMRA Document Number	References
2546508	2015, A Rationale in Support of a Request for Waiver from the Conduct of a Bioaccumulation Study in Fish with the E-3 Metabolite of Pyraflufen-ethyl, DACO: 9.5.6
2546499	2014, Assessment of the bioaccumulation of the E-3 metabolite of pyraflufen-ethyl using the BCFBAF v3.01 model, DACO: 9.5.6